message in a "Dear Doctor" letter to Health Care Professionals that explained it was adopting new labeling for its hormone therapy drugs in light of the WHI findings.

79. According to the January 6, 2003, "Dear Doctor" letter, the labeling changes include boxed warnings:

> [W]hich state that estrogens and estrogens plus progestin therapies should not be used for prevention of cardiovascular disease . . . The boxed warning also includes information [stating that because of the WHI study] . . . estrogens and estrogens plus progestin ***should be prescribed for the shortest duration consistent with treatment goals.***

(Emphasis added.)

80. In early June 2003, Wyeth commenced a new public marketing campaign with a full-page advertisement placed in 180 newspapers nationwide. The advertisement, *"A Message from Wyeth,"* disclosed that Wyeth was abandoning its decades-long strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions.

> Hormone therapy is not a lifelong commitment. As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) ***should be taken for the shortest duration*** at the lowest effective dose.

(*The Philadelphia Inquirer*, June 1, 2003, at C6; emphasis added).

81. Wyeth had recklessly and willfully failed to conduct adequate pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy. Nonetheless, Wyeth had promoted long-term hormone therapy use vigorously. The WHI and NCI studies could have and should have been conducted many years ago by Wyeth, before it began its long-term usage marketing campaign. Had it conducted the necessary studies and diligent post-marketing surveillance, Wyeth would have learned years ago that hormone therapy causes cardiovascular diseases, is marginally effective in preventing bone loss, does not promote well-being, causes a number of cancers and dementia, and is even harmful on a short-term basis by increasing the risk of breast cancer.

## IV. FRAUDULENT CONCEALMENT

82. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Wyeth. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part. Plaintiffs could not reasonably have discovered the dangerous nature of, and unreasonable adverse side effects associated with, Premarin, Provera, Prempro, and medroxyprogesterone acetate prior to July 9, 2002.

83. Wyeth was and is under a continuing duty to disclose to Plaintiffs the true character, quality, and nature of their hormone therapy drugs, including Premarin, Provera, Prempro, and medroxyprogesterone acetate. Because of their concealment of the true character, quality and nature of their hormone therapy drugs, Wyeth is estopped from relying on any statute of limitations defense.

## V. CAUSES OF ACTION

### COUNT I – NEGLIGENCE

84. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

85. At all relevant times, Wyeth had a duty to exercise reasonable care, and to comply with the existing standard of care, in its preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sales of its hormone therapy drugs, including Wyeth's Premarin, Prempro and medroxyprogesterone acetate, which they respectively introduced into the stream of commerce, including a duty to insure their hormone therapy drugs did not cause users to suffer from unreasonable, dangerous or untoward adverse side effects.

86. At all times relevant, Wyeth owed a duty to warn consumers of the risks, dangers, and adverse side effects of its hormone therapy drugs properly.

87. Wyeth breached their duty of care, and failed to exercise ordinary care in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of

their hormone therapy drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate, which it introduced into the stream of commerce, because Wyeth knew or should have known that its hormone therapy drugs created the risk of unreasonable, dangerous or untoward adverse side effects.

88. Wyeth knew, or in the exercise of reasonable care, should have known that its hormone therapy drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate were of such a nature that, if not properly prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold, they were likely to cause injury to those who took their drugs.

89. Wyeth breached its duty of care, and failed to use due care, in the manner in which it prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold its hormone therapy drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate, in that they:

(i) Failed to prepare its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(ii) Failed to design its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(iii) Failed to conduct adequate pre-clinical testing and research to determine the safety of its hormone therapy drugs;

(iv) Failed to conduct adequate post-marketing surveillance to determine the safety of its hormone therapy drugs;

(v) Failed to accompany its products with proper warnings regarding all possible adverse side effects associated with the use of its hormone therapy drugs and the comparative severity and duration of such adverse effects;

(vi) Failed to develop its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(vii) Failed to manufacture its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(viii) Failed to inspect its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(ix) Failed to label its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(x) Failed to market its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xi) Failed to promote its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xii) Failed to sell its hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;

(xiii) Failed to provide adequate training and information to healthcare providers for the appropriate use of its hormone therapy drugs;

(xiv) Failed to warn Plaintiff and her healthcare providers, prior to actively encouraging and promoting the sale of its hormone therapy drugs, either directly or indirectly, orally or in writing, about the following:

- the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, ovarian cancer, and other adverse side effects;
- the possibility of becoming disabled as a result of the use of the drugs;
- the adverse side effects associated with the use of the drugs, including, but not limited to, strokes, heart attacks, venous

thromboembolism, cardiovascular disease, breast cancer, and ovarian cancer; and,

(xv) Were otherwise careless and negligent.

90. Despite the fact that Wyeth knew or should have known that their hormone therapy drugs caused unreasonable and dangerous side effects, which many users would be unable to remedy by any means, they continued to promote and market their drugs to consumers, including Plaintiff Carol Levine, when there existed safer and more effective methods of countering the negative health effects of menopause, and of preventing osteoporosis and other disease states claimed by Wyeth to be prevented by its hormone therapy.

91. Wyeth knew or should have known that consumers generally, and Plaintiff Carol Levine specifically, would foreseeably suffer injury as a result of these Defendants' failure to exercise ordinary care.

92. Plaintiff Carol Levine is entitled to punitive damages because Wyeth's failure to warn was reckless and without regard for public safety and welfare. Wyeth misled both the medical community and the public at large, including Plaintiff Carol Levine, by falsely representing the safety of their products. Wyeth downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of hormone therapy drugs despite available information demonstrating that their products were likely to cause serious and sometimes fatal side effects to users.

93. Wyeth was or should have been in possession of evidence demonstrating that its products caused serious side effects. Nevertheless, Wyeth continued to market their products by providing false and misleading information with regard to their safety and efficacy.

94. Wyeth's actions described above were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff Carol Levine and the public.

95. As a result of Wyeth's conduct, Plaintiff Carol Levine suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT II – STRICT PRODUCTS LIABILITY**

96. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

97. Wyeth is manufacturer and/or supplier of hormone therapy drugs, and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

98. The hormone therapy drugs manufactured and/or supplied by Wyeth were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

99. The hormone therapy drugs were expected to and did reach Plaintiff Carol Levine without substantial change in condition. Alternatively, the hormone therapy drugs manufactured and/or supplied by Wyeth were defective in design or formulation, in that when they left the hands of the manufacturers and/or suppliers, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect.

100. The hormone therapy drugs manufactured and/or supplied by Wyeth were defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of it.

101. The hormone therapy drugs manufactured and/or supplied by Wyeth were defective due to inadequate post-marketing warning or instruction because, after Wyeth knew or should have known of the risk of injury from their hormone therapy drugs, they failed to provide adequate warnings to the medical community and women, and continued to promote the products as safe and effective.

102. The hormone therapy drugs were manufactured, distributed, tested, sold, marketed, advertised and represented defectively by the Defendants and such defects were substantial factors in bringing about the injuries to the Plaintiff Carol Levine.

103. As the direct and proximate cause of the defective condition of the hormone therapy drugs as manufactured and/or supplied by Wyeth, and of their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff Carol Levine suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT III – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

104. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

105. Wyeth is manufacturer and/or supplier of hormone therapy drugs, and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

106. The hormone therapy drugs manufactured and/or supplied by Wyeth were not accompanied by proper warnings to physicians, the medical community and women regarding all possible adverse side effects associated with the use of their hormone therapy drugs and the comparative severity and duration of such adverse effects.

107. The warnings and information given to the medical community and women did not accurately reflect the symptoms, scope or severity of the potential side effects.

108. Wyeth failed to perform adequate testing which would have shown that their hormone therapy drugs possessed serious potential side effects with respect to which full and proper warnings, accurately and fully reflecting symptoms, scope and severity, should have been made.

109. The hormone therapy drugs manufactured and/or supplied by Wyeth were defective due to inadequate post-marketing warning or instruction because, after Wyeth knew or should have known of the risk of injury and death from hormone therapy drugs, they failed to provide adequate warnings to physicians or consumers. And despite their inadequate post-marketing warnings and instructions to physicians, the medical community, and consumers, Defendants continued to promote the products aggressively.

110. Had adequate warnings or instructions been provided, Plaintiff Carol Levine would not have taken the drugs as she did, and would not have suffered harmful side effects.

111. As the direct and proximate cause of the defective condition of hormone therapy drugs as manufactured and/or supplied by Wyeth, Plaintiff Carol Levine suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT IV – BREACH OF IMPLIED WARRANTY**

112. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

113. In the design, manufacture, marketing, distribution and sale of Prempro, and in the provision of Prempro to Carol Levine, Defendants impliedly warranted to the public in general, and to Mrs. Levine in particular, that the Prempro designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law.

114. The Defendants breached their implied warranties of fitness and merchantability, insofar as Prempro was placed into the stream of commerce in such a manner as to constitute an unreasonable danger

and hazard to Carol Levine when used for its intended purpose. Contrary to such implied warranty, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold.

115. Plaintiff Carol Levine reasonably relied upon the skill and judgment of Wyeth as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.

116. As the direct and proximate cause of the breach of implied warranty, Plaintiff Carol Levine suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT V – BREACH OF EXPRESS WARRANTY**

117. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

118. In the design, manufacture, marketing, distribution and sale of Prempro, and in the provision of Prempro to Carol Levine, Defendants expressly warranted to the public in general, and to Mrs. Levine in particular, that the Prempro designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law, and were safe and efficacious when used as intended.

119. These warranties came in the form of: (i) publicly-made written and verbal assurances of the safety and efficacy of hormone therapy drugs by Wyeth, (ii) press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for hormone therapy drugs, which utterly failed to warn of the risks inherent to the ingestion of hormone therapy; (iii) verbal assurances made by Wyeth regarding hormone therapy, and the

downplaying of any risk associated with the drugs; (iv) false and misleading written information, supplied by Wyeth, and published in the *Physicians' Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing hormone therapy drugs during the period of Plaintiff's ingestion of hormone therapy drugs, including, but not limited to information relating the recommended duration of the use of the drugs; (v) promotional pamphlets and brochures published and distributed by Wyeth and directed to consumers; and (vi) advertisements. The documents referred to in this paragraph were created by and at the direction of Wyeth and, therefore, are in their possession and control.

120. The Defendants breached their express warranties of fitness and merchantability, insofar as Prempro was placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to Carol Levine when used for its intended purpose. Contrary to such express warranties, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold. As such, Wyeth's products were neither in conformity to the promises, descriptions or affirmations of fact made about these drugs nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

121. Wyeth thereafter breached its express warranties to Plaintiff Carol Levine in violation of the applicable provisions of the state Uniform Commercial Code as amended by: (i) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Carol Levine in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiff Carol Levine or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties; (ii) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Carol Levine, which failed to counteract the negative health effects of menopause in a safe and permanent manner and without injury; and (iii) manufacturing, marketing,

packaging, labeling, and selling hormone therapy to Plaintiff Carol Levine, thereby causing her serious physical injury and pain and suffering.

122. Plaintiff Carol Levine reasonably relied upon the skill and judgment of Wyeth as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.

123. As the direct and proximate cause of the breach of expressed warranty, Plaintiff Carol Levine suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT VI – FRAUD**

124. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

125. Wyeth, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone therapy drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate, owed a duty to provide accurate and complete information regarding these products.

126. Wyeth's advertising programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the impression that the use of their hormone therapy drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate, were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

127. Wyeth intentionally encouraged women in general, including Plaintiff Carol Levine, to remain on hormone therapy for a longer period of time than Wyeth knew or should have known was safe and effective.

128. Wyeth purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of hormone therapy. Wyeth, through promotional

literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying known adverse and serious health effects. Wyeth falsely and deceptively kept relevant information from potential hormone therapy users and minimized prescriber concerns regarding the safety and efficacy of its drugs.

129. Plaintiff Carol Levine justifiably relied to her detriment upon Wyeth's intentional misrepresentations concerning its hormone therapy drugs.

130. In particular, in the materials disseminated by Wyeth, it falsely and deceptively misrepresented or omitted a number of material facts regarding its hormone replacement drugs, including Premarin, Prempro, Provera and medroxyprogesterone acetate, including, but not limited to, the following:

(I) The presence and adequacy of the testing of its hormone therapy drugs, both pre-and post-marketing; and,

(ii) The severity and frequency of adverse health effects caused by is hormone therapy drugs.

131. Plaintiff Carol Levine is entitled to punitive damages because the failure of Wyeth to warn was reckless and without regard for the public's safety and welfare. Wyeth misled both the medical community and the public at large, including Plaintiff Carol Levine, by making false representations about the safety of its hormone therapy drugs.

132. Wyeth was or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, Wyeth continued to market their products by providing false and misleading information with regard to their safety and efficacy.

133. Wyeth's actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff Carol Levine and the public.

134. As a result of Wyeth's conduct, Plaintiff Carol Levine suffered these injuries as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT VII – CORPORATE RESPONSIBILITY: JOINT VENTURES, PARENT/SUBSIDIARIES, AND/OR SUCCESSOR CORPORATION**

135. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

136. As a result of their participation in various joint ventures, parent/subsidiary relationships, and/or successor corporations, Wyeth is liable to Plaintiffs.

137. As a result of their negligent supervision and actual supervision of various joint ventures, parent/subsidiary relationships, and/or successor corporations, Wyeth is liable to Plaintiffs.

138. As a result of the invalidity of various indemnification agreements, Wyeth is liable to Plaintiffs.

139. Wyeth is liable to Plaintiffs, as alter egos of their joint ventures, parent/subsidiary relationships, and/or successor corporations.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**COUNT VIII – LOSS OF CONSORTIUM**

140. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

141. Plaintiff Larry Levine was at all times relevant hereto the spouse of Plaintiff Carol Levine, and lived and cohabited with her.

142. Mr. Levine has necessarily paid and has become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

143. Mr. Levine has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society, and the ability of Mrs. Levine, has in those respects been impaired and depreciated, and the marital association between husband and wife has been altered and, accordingly, has been caused great mental anguish.

144. Mr. Levine is entitled to punitive damages because Wyeth's failure to warn was reckless and without regard for the public's safety and welfare. Wyeth misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of its products. Wyeth downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of hormone therapy, despite available information demonstrating its products were likely to cause serious and sometimes fatal side effects to its users.

145. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs Mr. and Mrs. Levine pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars ($10,000,000.00) in compensatory damages, and Twenty Million Dollars ($20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

**DEMAND FOR JURY TRIAL**

Plaintiffs Elaine and Larry Levine hereby demand a jury trial on all claims so triable in this action.

Respectfully submitted,

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